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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/550,103	04/14/2000	Richard C. Deth	NU-431AX	8235

207 7590 10/02/2002

WEINGARTEN, SCHURGIN, GAGNEBIN & LEOVICI LLP  
TEN POST OFFICE SQUARE  
BOSTON, MA 02109

EXAMINER
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WEGERT, SANDRA L

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 10/02/2002

9

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application N .

09/550,103

Applicant(s)

DETH, RICHARD C.

Examiner

Sandra Wegert

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 21 June 2002.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) 1-4 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 5-9 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Status of Application, Amendments, and/or Claims***

The amendment filed 21 June 2002 (Paper No. 8) has been entered. Claim 5 has been amended. Claims 1-4 are non-elected. Claims 5-9 are under examination.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Withdrawn Objections and/or Rejections***

### ***Sequence Rules***

The request that Figure 1 be given a SEQ ID NO, as put forth in the previous Office Action (4/23/02, Paper 7) is *withdrawn* in light of the *previous* Amendment (8/24/01, Paper 3) which had inserted a SEQ ID NO into the figure.

### ***Continuity Data***

The requirement that the filing history listed in the Specification be updated, as set forth at page 3 of the previous Office Action (Paper No. 7, 23 April 2002), is *withdrawn* in view of Applicant's amendment that updated the continuity information on page 1 of the Specification (Paper 8, 6/21/02).

***35 USC § 102***

The rejection of Claims 5-9 under 35 USC 102(b) as being unpatentable over Deth, et al (April 1, 1996, Biol. Psychiatry, 39: 504) is *withdrawn* in view of the letter submitted by the Editor of the journal Biological Psychiatry, that the cited volume was not made available to the public until April 9, 1996, and furthermore, that the article is authored by the same Inventor as the instant Application.

**Objections and/or Rejections**

***35 USC § 112, First Paragraph – Scope of Enablement***

Claims 5-9 are rejected under 35 U.S.C. 112, first paragraph, because the Specification, while being enabling for a method identifying therapeutic agents for neuropsychiatric diseases involving the D4 receptor and in which phospholipid methylation has been shown to be affected, does not reasonably provide enablement for agents or processes involving other neuropsychiatric diseases in which a clear link from the D4 receptor to phospholipid methylation has not been established. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

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Claims 5-9 are drawn to a method of identifying a therapeutic process or agent for treating schizophrenia or a related neuropsychiatric disorder by using a cell line comprising the dopamine D4 receptor, and measuring levels of phospholipid methylation in the cells before and after administration of the candidate agent.

The specification discloses that phospholipid methylation is compromised in schizophrenic patients and that dopamine D4 receptors mediate the effect of dopamine on phospholipid methylation. Data is presented that demonstrates stimulation as well as inhibition of phospholipid methylation using agonists and antagonists of the D4 receptor.

However, a sufficient amount of direction or guidance is lacking in claims 5-9. The claims recite a method of determining whether an agent affects phospholipid methylation mediated by the disclosed D4 receptor. However, the Specification does not disclose a link between neuropsychiatric disorders other than schizophrenia and phospholipid methylation. Furthermore, there is no link established between other neuropsychiatric disorders and the D4 receptor.

In In re Wands, 8USPQ2d, 1400 (CAFC 1988) page 1404, the factors to be considered in determining whether a disclosure would require undue experimentation include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

Due to the large quantity of experimentation required to determine which neuropsychiatric disorders involve phospholipid methylation and the dopamine D4 receptor, and

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then to search for agents that modulate phospholipid methylation, the lack of direction or guidance in the specification regarding same, the lack of working examples to other diseases with perturbed phospholipid methylation involving the D4 receptor, the state of the art showing the unpredictability of diagnosing neurological disorders, and the breadth of the claims which embrace innumerable neuropsychiatric diseases, undue experimentation would be required of the skilled artisan to make and use the claimed invention in its full scope.

**Conclusion:** Claims 5-9 are not allowable for the reasons cited above.


***Advisory Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Wegert whose telephone number is (703) 308-9346. The examiner can normally be reached Monday - Friday from 9:00 AM to 5:00 PM (Eastern Time). If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Kunz, can be reached at (703) 308-4623.

Official papers filed by fax should be directed to (703) 308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

SLW

9/29/02

  
**GARY KUNZ**  
**SUPERVISORY PATENT EXAMINER**  
**TECHNOLOGY CENTER 1600**